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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/440,384	11/15/1999	HOWARD A. KINGSFORD	05918-153001	2883

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FISH & RICHARDSON PC
225 FRANKLIN ST
BOSTON, MA 02110

EXAMINER

PATTERSON, MARC A

ART UNIT	PAPER NUMBER
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1772

DATE MAILED: 08/08/2003

24

Please find below and/or attached an Office communication concerning this application or proceeding.

AS-24

Office Action Summary	Application No. 09/440,384	Applicant(s) KINGSFORD, HOWARD A.	
	Examiner Marc A Patterson	Art Unit 1772	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 02 June 2003.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 2-23 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 2-23 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
 If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
 a) ☐ All b) ☐ Some * c) ☐ None of:
 1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
 * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
 a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

WITHDRAWN REJECTIONS

1. The 35 U.S.C. 112 second paragraph rejection of Claim 19, of record on page 19 of the previous Action, is withdrawn.

NEW REJECTIONS

Claim Rejections - 35 USC § 112

2. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

3. Claim 19 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Claim 19 recites the limitation "a surrounding surface of" in line 3. There is insufficient antecedent basis for this limitation in the claim.

Claim Rejections - 35 USC § 102

4. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

5. Claims 4, 10, 16 – 17, 19 – 20 and 23 are rejected under 35 U.S.C. 102(b) as being anticipated by Reed et al. (U.S. Patent No. 5,312,456).

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With regard to Claim 19, Reed et al. disclose an array (plurality) of surfaces having a pointed shape (therefore a tip; column 3, lines 16 – 22; column 60 – 66) formed of plastic (column 3, lines 40 – 42) which is used to pierce (penetrate) skin (column 4, lines 28 – 32); it is therefore a skin attachment member of plastic resin, and is configured to penetrate into the epidermal skin layer; the skin attachment has a sheet form backing from which the penetrating elements extend integrally (base; column 7, lines 26 – 27), and is used as a bandage (column 5, lines 21 – 26); the skin penetrating elements include a retention barb extending from an outer surface of the skin penetrating element (a barb which bonds with skin; column 4, lines 28 – 34); the skin penetrating elements are integral with the backing (column 3, lines 32 – 34) and are made of a rigid material comprising plastic (column 3, lines 39 – 41); the claimed aspect of the ‘array of skin penetrating elements’ being formed ‘integrally from a single plastic resin’ therefore reads on Reed et al.

With regard to Claim 4, the surfaces of the skin penetrating elements have pointed shapes (column 3, lines 16 – 22; column 60 – 66), and therefore, pointed tips.

With regard to Claim 10, each skin penetrating element includes two barbs (column 3, lines 60 – 66, Figure 6).

With regard to Claim 16, the scope of the claim falls within the limitation of Reed et al. as discussed above. The process of making the skin attachment member (product – by – process) is given little patentable weight. Applicant would need to demonstrate, by verified showing, the unexpected advantages accruing from making the elements by molding as claimed.

With regard to Claim 17, the skin penetrating elements have pointed shapes, and therefore define depressions on the surface.

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With regard to Claim 20, as stated previously, the penetrating element has a pointed shape; it therefore tapers continuously from the base to the tip.

With regard to Claim 23, as stated previously, the barb extends from the outer surface of the penetrating element; it therefore has a lower surface disposed substantially perpendicular to a central axis of the skin penetrating element from which it extends.

Claim Rejections - 35 USC § 103

6. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

7. Claims 2 – 3, 5 – 9, 11 – 12, 18 and 21 – 22 are rejected under 35 U.S.C. 103(a) as being unpatentable over Reed et al. (U.S. Patent No. 5,312,456).

Reed et al disclose a skin penetrating element as discussed above. With regard to Claims 2 – 3, 5 – 9, 11 – 12 and 18, Reed et al. fail to disclose a skin penetrating element comprising a cone – shaped body, and a cone – shaped body having a diameter of about 0.003”, and a skin penetrating element having a diameter of 0.003”, and a skin penetrating element having a length of 0.012” and a backing having a thickness of 0.003 to 0.008”, and a retention barb which is 0.008” to 0.0095” from the backing, and a retention barb with a length of 0.0001”, and a retention barb which tapers from a thickness of 0.0001” to a point at an angle of 72 degrees, and a skin attachment member having a density of 400 skin penetrating elements in a 0.1 in² area and the elements are spaced apart from each other a distance of 0.003, and the elements are

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perpendicular to the backing. However, the shape of the skin penetrating elements (including diameter), the length of the elements, the thickness of the backing, the location of the retention barb, the length of the retention barb, the angle and thickness from which the retention barb tapers, the density and spacing of skin penetrating elements, and the angle of the elements relative to the backing would be readily determined through routine experimentation by one having ordinary skill in the art depending on the desired end result. *In re Boesch and Slaney*, 205 USPQ 215 (CCPA 1980).

With regard to Claims 21 and 22, Reed et al. fail to disclose a skin penetrating element comprising barbs which are disposed at different distances from the base, and which define a half – pyramidal shape. However, Reed et al. disclose an element having barbs which are disposed at the same distance from the base (column 3, lines 60 – 66) and a barb width of 1 μm (column 3, lines 47 – 59). Therefore, one of ordinary skill in the art would have recognized that the shape and the distances of the barbs would be readily determined through routine experimentation by one having ordinary skill in the art depending on the desired end results as evidenced by Reed et al. Thus, it would be obvious for one of ordinary skill in the art to vary the distances of the barbs from the base and the width of the barb (which will determine whether it has a half – pyramidal shape) since the distances of the barbs from the base and the width of the barb would be readily determined through routine experimentation by one having ordinary skill in the art depending on the desired end result. *In re Boesch and Slaney*, 205 USPQ 215 (CCPA 1980).

8. Claim 13 is rejected under 35 U.S.C. 103(a) as being unpatentable over Reed et al. (U.S. Patent No. 5,312,456) in view of Fye (U.S. Patent No. 5,031,609).

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Reed et al disclose a skin – attachment member as discussed above. With regard to Claim 13, Reed et al. fail to disclose a skin attachment member comprising nylon.

Fye teaches the use of nylon in the making of bandages, for the purpose of making bandages which are light – weight and hand – washable (column 2, lines 34 – 39).

Since Reed et al and Fye, both, teach fastening to skin (column 5, lines 21 – 26 of Reed et al; column 2, lines 34 – 39 of Fye) one of ordinary skill in the art would have recognized the usage of nylon for making bandages which are light – weight and hand – washable, to use repeatedly by washing as taught by Fye, to save money.

It therefore would have been obvious for one of ordinary skill in the art at the time Applicant's invention was made to have provided for nylon in Reed et al. in order to make bandages which are hand – washable as taught by Fye.

9. Claims 14 – 15 are rejected under 35 U.S.C. 103(a) as being unpatentable over Reed et al. (U.S. Patent No. 5,312,456) in view of Coates (U.S. Patent No. 4,219,019).

Reed et al disclose a skin – attachment member as discussed above. With regard to Claims 14 and 15, Reed et al. fail to disclose a skin attachment member comprising polyethylene terephthalate.

Coates teaches that polyethylene terephthalate is notoriously well known in the art in the making of bandages (column 5, lines 14 – 19), since polyethylene terephthalate possesses bulk and conformability in the bandage art (column 1, lines 60 – 63). The desirability of providing for polyethylene terephthalate in Reed et al, which is a bandage, would therefore have been obvious to one of ordinary skill in the art.

It therefore would have been obvious for one of ordinary skill in the art at the time Applicant's invention was made to have provided for polyethylene terephthalate in Reed et al. in order to make bandages which possesses bulk and conformability as taught by Coates.

ANSWERS TO APPLICANT'S ARGUMENTS

10. Applicant's arguments regarding the 35 U.S.C. 112 second paragraph rejection of Claim 19, of record on page 2 of the previous Action, have been considered and have been found to be persuasive. The rejections are therefore withdrawn.

Applicant's arguments regarding the 35 U.S.C. 103(a) rejection of Claims 2 – 12 and 16 – 23 as being unpatentable over Reed et al. (U.S. Patent No. 5,312,456), 35 U.S.C. 103(a) rejection of Claim 13 as being unpatentable over Reed et al. (U.S. Patent No. 5,312,456) in view of Fye (U.S. Patent No. 5,031,609) and 35 U.S.C. 103(a) rejection of Claims 14 – 15 as being unpatentable over Reed et al. (U.S. Patent No. 5,312,456) in view of Coates (U.S. Patent No. 4,219,019), of record on page 2 of the previous Action, have been considered but have not been found to be persuasive for the reasons set forth below.

Applicant argues, on page 5 of Paper No. 23, that Reed et al fails to teach an array of skin penetrating elements which is formed integrally from a single plastic resin. However, as stated in the new rejection above, the skin penetrating elements disclosed by Reed et al are integral with the backing are made of a rigid material comprising plastic; the claimed aspect of the 'array of skin penetrating elements' being formed 'integrally from a single plastic resin' therefore reads on Reed et al. It is also noted that an omission has been made in the marked – up copy of amended Claim 19; the phrase 'is molded' has been amended to 'is formed,' but the change is not indicated in the marked – up copy.

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11. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.

Conclusion

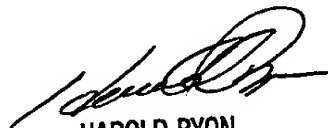
12. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Marc Patterson, whose telephone number is (703) 305-3537. The examiner can normally be reached on Monday through Friday from 8:30 AM to 5:00 PM. If attempts to reach the examiner by phone are unsuccessful, the examiner's supervisor, Harold

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Pyon, can be reached at (703) 308-4251. FAX communications should be sent to (703) 872-9310. FAXs received after 4 P.M. will not be processed until the following business day.

Marc A. Patterson, PhD.

Marc Patterson
Art Unit 1772


HAROLD PYON
SUPERVISORY PATENT EXAMINER
1772

8/7/03